

**REMARKS/ARGUMENTS**

By this Amendment, Claims 2, 9, 14-15, 17-18, 22, 38, 45, 51, 56 are amended. Thus, Claims 1-70 are currently pending.

The Examiner has rejected Claims 22-25 and 38-43 under 35 U.S.C. §112, second paragraph as being indefinite and, in particular, the omission of structural cooperative relationship regarding the “driver” of Claim 9 and the “rod” of Claims 22-25. To that end, Applicant has amended Claim 22 to specify that the driver 300 (rather than the “injector”) further comprises a rod 320 as defined in Claims 22-25, as disclosed in Fig. 14 and related text on p. 19, lines 10-24. Similarly, Claim 38 has been amended to specify that the rod forms a portion of the driver. In view of these amendments, Applicant respectfully requests that the §112 rejection be withdrawn.

The Examiner has rejected Claims 1-31, 35-36, 44-46, 69 and 70 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2003/0229314 (McWethy, et al.). With particular regard to Claim 1, the Examiner states:

With regards to claims 1, 9, 44 and 45, McWethy discloses (figure 1-21) an injection device comprising: a housing (50) having a proximate end (near 52) and a distal end, the distal end (near 51) having an opening therein; a shield (2) slideably coupled to the housing and having a shield base (21) and aperture (33) positioned at said distal end thereof; a cartridge barrel (30) within the housing, the cartridge barrel having proximate and distal ends; a needle cannula (12) fixed to the distal end of the cartridge barrel, or attachment means for fixing a needle cannula to the distal end, said needle cannula being disposed within said shield prior to activation of said device; a stopper (38) within the cartridge barrel; a driver (42) coupled to the stopper; a spring (24) coupled between the housing and the driver; an automatic driver trigger (46, figures 5 and 6) for retaining the driver fixed to the housing and in which state the spring is in a compressed state, the trigger being actuable by displacing said shield towards said proximal end of housing, thereby permitting passage of said needle cannula through said aperture, said actuated trigger automatically releasing the driver from the housing thereby allowing the spring to urge the driver through the housing and with it the stopper through the cartridge barrel; and a release mechanism (26) for releasing the spring from the driver at some point on its travel through the housing, whereupon the spring engages the shield base and automatically urges the shield away from the housing so as to cover the needle cannula. (Office Action, p. 3-4 of June 23, 2009).

Applicants respectfully disagree for the following reasons.

Although the Examiner asserts that all of the elements of Claims 1, 9, 44 and 45 are already disclosed in McWethy, McWethy fails to disclose the following element of those claims:

..said needle cannula being disposed within said shield prior to activation of said device.. (Claim 1);

..said needle being disposed within said shield prior to displacement of said shield.. (amended Claim 9);

said needle cannula being disposed within said shield prior to activation of said injector.. (Claim 44);

said needle being disposed within said shield prior to displacement of said shield.. (amended Claim 45);

As clearly shown in Fig. 4<sup>1</sup> of McWethy, the needle 12 is completely exposed prior to activation of the injector 10 whose barrel 20 is completely located aft of the needle 12. The barrel 20 of McWethy does not provide any covering or shield function to the needle prior to activation of the injector 10 or prior to barrel 20 displacement (which is only triggered by displacement of the plunger 40 which in turn eventually displaces a cylindrical collar 46 to release latches 27 and retaining arms 26 to deploy barrel 20). In contrast, in the present invention, as explained previously by the Applicant, the shield 200 (present application, Fig. 3) or 250 (present application, Fig. 4) surrounds the needle prior to the injector activation, initiated by shield displacement. Thus, Claims 1, 9, 44 and 45 are patentable over McWethy.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, the cartridge holder 50/150/250/350 of McWethy does not appear to be driven through any housing. Rather, it is only the movement of the plunger 40/140/240/340 of McWethy within the

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<sup>1</sup> See also paragraph 0010 describing Fig. 4 which depicts the injector prepared for injection.

cartridge holder until the barrel 20/120/220/320 is deployed. Thus, for all of these reasons, Claim 2 is patentable thereover.

Claim 3 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, as discussed previously, activation or deployment of the barrel 20/120/220/320 of McWethy occurs by the release of the retaining latches 27 and retaining arms 26, not because of any movement of the barrel 20. Thus, for all of these reasons, Claim 3 is patentable thereover.

Claim 4 is dependent upon Claim 3 and is patentable for the same reasons. Furthermore, since the needle 12 is already exposed prior to the activation of any part of the injector 10 of McWethy, there is no “emergence of the needle cannula from the barrel 20” in McWethy. Thus, for all of these reasons, Claim 4 is patentable thereover.

Claim 5 is dependent upon Claim 3 and is patentable for the same reasons. Furthermore, the “trigger” of McWethy has nothing to do with the emergence of the needle because the trigger is operated off of the plunger 40 being driven such that the cylindrical collar 46 contacts and deforms the release latches 27 and release arms 26. Thus, for all of these reasons, Claim 5 is patentable thereover.

Claim 6 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 7 is dependent upon Claim 1 and is patentable for the same reasons. In addition, the barrel 20 of McWethy does not move into any housing. Thus, for all of these reasons, Claim 7 is patentable thereover.

Claim 8 is dependent upon Claim 1 and is patentable for the same reason.

Claim 10 is dependent upon Claim 9 and is patentable for the same reasons. Furthermore, paragraph 0038 of McWethy does not disclose barrel 20 displacement nor driver disengagement requiring a substantial force over a short travel distance. Thus, for all of these

reasons, Claim 10 is patentable thereover.

Claim 11 is dependent upon Claim 10 and is patentable for the same reasons. In addition, McWethy does not disclose the substantial force of Claim 10 as being approximately 1 kgf. Thus, Thus, for all of these reasons, Claim 10 is patentable thereover.

Claim 12 is dependent upon Claim 10 and is patentable for the same reasons. In addition, there is no “shield travel” in McWethy. Rather, after injection, “the needle is automatically retracted into the barrel” (Abstract, McWethy). So it is not the barrel that is traveling. Thus, for all of these reasons, Claim 12 is patentable thereover.

Claim 13 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 14 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 15 is dependent upon Claim 14 and is patentable for the same reasons.

Claim 16 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 17 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 18 is dependent upon Claim 17 and is patentable for the same reasons. Furthermore, McWethy uses no cartridge supports for detecting the end of the cartridge. Rather, the retraction of the needle 12 occurs when the cylindrical collar 46 of the plunger 40 deforms the release latches 27 and release arms 26. Thus, for all of these reasons, Claim 18 is patentable thereover.

Claim 19 is dependent upon Claim 9 and is patentable for the same reasons. Furthermore, as stated in the Abstract of McWethy, it is not the barrel 20 that is moved into a needle shielded position but rather it is the retraction of the cartridge holder 50 within the barrel 20 that occurs. Thus, for all of these reasons, Claim 19 is patentable thereover.

Claim 20 is dependent upon Claim 19 and is patentable for the same reasons.

Claim 21 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 22 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 23 is dependent upon Claim 22 and is patentable for the same reasons.

Claim 24 is dependent upon Claim 22 and is patentable for the same reasons.

Claim 25 is dependent upon Claim 23 and is patentable for the same reasons.

Claim 26 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 27 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 28 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 29 is dependent upon Claim 28 and is patentable for the same reasons.

Furthermore, elements 360/362 of McWethy are locking clips and do not form leaf springs.

Thus, for all of these reasons, Claim 29 is patentable thereover.

Claim 30 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 31 is dependent upon Claim 21 and is patentable for the same reasons.

Furthermore, in McWethy there is no movement of the barrel 20 but rather only movement of the cartridge holder 50 within the barrel 20. Thus, for all of these reasons, Claim 31 is patentable thereover.

Claim 35 is dependent upon Claim 28 and is patentable for the same reasons.

Furthermore, in McWethy the outer circumference wall of the barrel 20 is not in any sliding relationship with any housing inner circumferential wall. Thus, for all of these reasons, Claim 35 is patentable thereover.

Claim 36 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 46 is dependent upon Claim 45 and is patentable for the same reasons.

Furthermore, paragraph 0038 of McWethy does not disclose barrel 20 displacement nor driver

disengagement requiring a substantial force over a short travel distance. Thus, for all of these reasons, Claim 46 is patentable thereover.

Claim 47 is dependent upon Claim 46 and is patentable for the same reasons.

Claim 48 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 49 is dependent upon Claim 48 and is patentable for the same reasons.

Claim 50 is dependent upon Claim 45 and is patentable for the same reasons. Furthermore, in McWethy there is no movement of the cartridge holder 50 toward any distal end of the automatic injector. As explained earlier, in McWethy, only the plunger 40 moves within the cartridge holder 50. Thus, for all of these reasons, Claim 50 is patentable thereover.

Claim 51 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 52 is dependent upon Claim 51 and is patentable for the same reasons.

Claim 53 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 54 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 55 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 56 is dependent upon Claim 55 and is patentable for the same reasons. Furthermore, as mentioned previously, McWethy uses no cartridge supports for detecting the end of the cartridge. Rather, the retraction of the needle 12 occurs when the cylindrical collar 46 of the plunger 40 deforms the release latches 27 and release arms 26. Thus, for all of these reasons, Claim 56 is patentable thereover.

Claim 57 is dependent upon Claim 55 and is patentable for the same reasons.

Claim 58 is dependent upon Claim 45 and is patentable for the same reasons. Furthermore, as mentioned earlier, in McWethy there is no movement of the barrel 20. Rather, it is the retraction of the cartridge holder 50 that occurs. Thus, for all of these reasons, Claim 58 is

patentable thereover.

Claim 59 is dependent upon Claim 58 and is patentable for the same reasons.

Claim 60 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 61 is dependent upon Claim 60 and is patentable for the same reasons.

Claim 62 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 63 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 64 is dependent upon Claim 63 and is patentable for the same reasons.

Claim 65 is dependent upon Claim 63 and is patentable for the same reasons.

Furthermore, McWethy does not disclose the use leaf springs. Thus, for all of these reasons, Claim 65 is patentable thereover.

Claim 66 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 69 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 70 is dependent upon Claim 45 and is patentable for the same reasons.

The Examiner has rejected Claims 32-34, 37, 67 and 68 under 35 U.S.C. §103(a) as being unpatentable over McWethy in view of U.S. Patent No. 5,114,406 (Gabriel). In particular, the Examiner asserts that McWethy discloses (figure 1-21, as quoted from the Examiner above) the automatic injector of Claims 28, 32 and 63; however, the Examiner agrees that McWethy fails to disclose wherein the housing and shield further include a window arranged to allow viewing of the barrel, a barrel scale and the fluid in the barrel. To make up for that deficiency, the Examiner asserts that Gabriel discloses a viewing window (33) and that it would have been obvious to a person of ordinary skill in the art to modify the McWethy device as disclosed by Gabriel in view of the cartridge contents.

Applicants respectfully disagree for the following reasons.

Claim 32 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 33 is dependent upon Claim 32 and is patentable for the same reasons. Furthermore, Gabriel does not disclose the use of two matching slots in conjunction with forming the window. Thus, for all of these reasons, Claim 33 is patentable thereover.

Claim 34 is dependent upon Claim 32 and is patentable for the same reasons. Furthermore, Gabriel does not disclose the use of two matching openings in conjunction with forming the window. Thus, for all of these reasons, Claim 34 is patentable thereover.

Claim 37 is dependent upon Claim 33 and is patentable for the same reasons.

Claim 67 is dependent upon Claim 63 and is patentable for the same reasons.

Claim 68 is dependent upon Claim 67 and is patentable for the same reasons. Furthermore, as mentioned earlier, Gabriel does not disclose the use of two matching openings in conjunction with forming the window. Thus, for all of these reasons, Claim 68 is patentable thereover.

The Examiner has provisionally rejected Claims 1-70 based on obviousness-type double patenting as being unpatentable over Claims 1-18 of copending Application Serial No. 10/566,333. To that end, Applicants submit herewith a Terminal Disclaimer to overcome that rejection.

The Examiner has also provisionally-rejected Claims 1-70 on obviousness-type double patenting as being unpatentable over Claims 1-24 of Application Serial No. 11/666,851.

Applicants traverse this double patenting rejection based on the following reasons.

The present application has a priority date of July 31, 2003 (ASN 60/491,196) and November 12, 2003 (ASN 60/518,936) which is before the priority date of ASN 11/666,851 which is November 4, 2004 (ASN 624,864). Thus, ASN 11/666,851 is not even prior art to the



present application.

Secondly, the invention of ASN 11/666,851 uses two springs, one for delivery of the drug (“drive member drive spring”) and the second for shielding (“shield drive spring”). In contrast, the present invention uses only one spring.

Thirdly, the mode of activation is different in the two inventions. The invention of ASN 11/666,851 does not activate upon displacement of the shield toward the proximate end of the housing, as in the present invention, but rather uses an axial force to a trigger 110 (11/666,851, US Patent Publication No. 2007/0265568, paragraph 0052).

Thus, the present invention is patently distinct from the invention of ASN 11/666,851.

Claim 56 in Applicants’ last-filed amendment included a status identifier “Original” but the word “cartridge” was being deleted to comply with amended antecedent basis in Claim 55. To that end, Applicant has indicated Claim 56 in this amendment as “Currently Amended” with the word “cartridge” being deleted to make sure this amendment is entered properly.

Thus, Applicants respectfully submit that Claims 1-70 are now in condition for allowance. Accordingly, prompt and favorable examination on the merits is respectfully requested.

Application Serial No. 10/566,333  
Attorney Docket No. S2082/20004  
Amendment Dated September 24, 2009

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

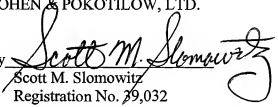
Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.

September 24, 2009

Please charge or credit our  
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By

  
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Scott M. Slomowitz